

ABSTRACT

[0138] Structure and methodology for reducing risk of protocol ambiguities that could lead to operational failures in the conduct of clinical trials. Roughly described, an analyst encodes the features of a protocol into a highly structured, formal model created specifically to capture issues that tend to cause operational difficulties. The process forces the analyst to look for specific parameters in the text version of the protocol. The system creates a database of the protocol as encoded, and can display the protocol schema as a graphical network of protocol events and temporal links. In one aspect, the database includes an object class into which an analyst encodes descriptions of operational uncertainties. The system can display the network in graphical-visual form, with a human-perceptible indication of objects that have operational uncertainties associated therewith. Advantageously, the formal protocol model includes slots for encoding temporal constraints among protocol events.